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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,427	01/12/2004	Lee Bolduc	203-2626 DIV CON VIII (24)	9695
7590 Mark Farber, Esq. U.S. Surgical, A Division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 08/24/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,427	<b>Applicant(s)</b> BOLDUC ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received 06/09/2010.

The examiner acknowledges the amendments made to the claims.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claims 1, 19, 28 there is an inconsistency in the language of the preamble and that of body of the claim thus making their scope unclear. The preamble recites an applicator with the fasteners only functionally recited, e.g. for attaching fasteners, thus indicating that the claims are directed to the subcombination, applicator. However line 5 of claim 1, line 4 of claim 19, and line 2 of claim 28 positively recite the fasteners, as an element of the invention, e.g. a plurality of fasteners, thus indicating that the claims are directed to the combination of the applicator and the fasteners. As such it is unclear whether applicant intends the claims to be drawn to the combination or the subcombination. Applicant is hereby required to indicate which, the combination (applicator and the fasteners) or subcombination (fasteners) the claims are intended to be drawn and make the language consistent with this intent. For examination purposes, the claims will be considered as drawn to the

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combination, applicator and the fasteners.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

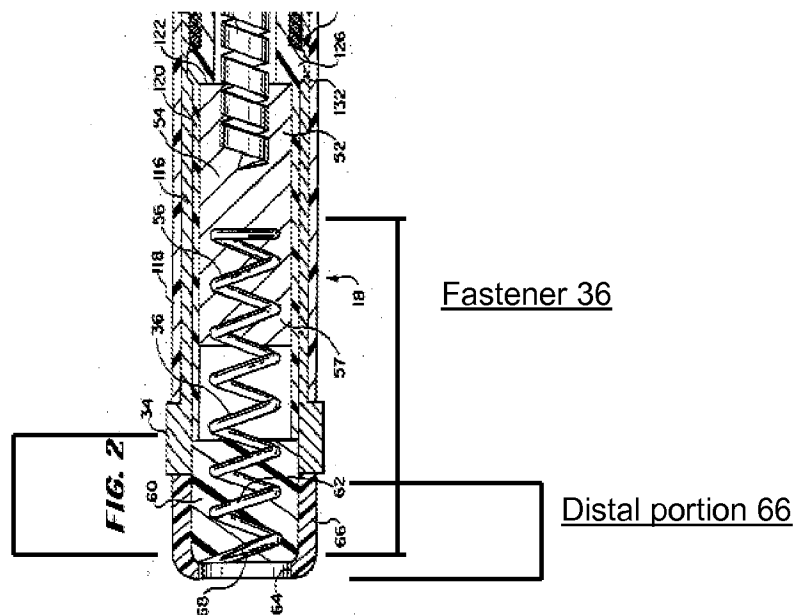
5. Claims 1, 4-6, and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**).

Claims 1, 4-6 and 19-30: Miller discloses an applicator comprising a distal portion having an elongate outer tube **66**, a connecting end and a terminal end, a proximal portion having a handle and an actuator **22**, the proximal portion being attached to the connecting end of the distal portion, and a rotator **60** cooperating with the actuator (as it facilitates advancement of a fastener), wherein a “rotator” is “a thing that causes something to rotate,” or guides and ejects through a helical path, the rotator including a longitudinal groove **62** extending along at least a portion thereof (at least one turn on rotator **60**), the groove configured to receive a portion of a fastener **36**, wherein the rotator resides within and extends substantially the length of the outer tube such that actuation of the actuator results in rotation and translation of the fastener relative to the outer tube while the rotator remains longitudinally or axially stationary with respect to the outer tube (Figures 1-3; col. 5, line 57 to col. 6, line 22). The applicator has a thread

form **62** (distal turns on rotator **60**) contained in an interior of the terminal end adapted to engage a plurality of fasteners wherein the thread form is an interlock spring fixedly retained in the interior of the terminal end, wherein “spring” is taken to mean an element that imparts an “actuating force.” A nose piece **54** is attached to a terminal end having a structure projecting perpendicular toward a longitudinal axis of the outer tube and may engage a plurality of fasteners. The longitudinal groove is adapted to slidably receive the portion of the fasteners, and at least a portion of the fasteners (proximal to the rotator **60**) surrounds the rotator, and the longitudinal groove being formed on an outer surface of the rotator (on the outer sides where the fastener **36** enters and exits the rotator).

**Figure 2, Miller**

Rotator 60 with longitudinal groove 62, wherein a rotator is “a thing that causes something to rotate”



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Miller discloses a fastener **36** ("bipolar pacing lead corkscrew") but lacks a plurality of fasteners, although the rotator is adapted to receive a plurality of fasteners for multiple actuations. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of fasteners or a set of leads for delivery with Miller's applicator for further stimulation of tissue.

Miller does not disclose that at least one fastener is formed from an absorbable material. However, it was well known in the art that absorbable materials are biocompatible and, therefore it would have been obvious to one of ordinary skill in the art to form the fastener of a material that is absorbable since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

6. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Smith et al.** (U.S. Patent No. **4,596,350**).

Claims 2-3: Miller discloses the claimed device, except for a lock/clip indicator for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring for applying longitudinal forces against the lock/clip indicator.

Smith et al. teach a lock/clip indicator **51** for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring **20** for applying longitudinal forces against the lock/clip indicator (col. 9, lines 35-52). It would

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have been obvious to one of ordinary skill in the art at the time of invention to provide a lock/clip indicator and load spring, as taught by Smith et al., to Miller since it was known in the art that lock/clip indicators with spring mechanisms prevent undesirable forward advancement of fasteners.

7. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Green et al.** (U.S. Patent No. **5,100,420**).

Claims 7-8: Miller discloses the claimed device, except for the distal portion and the proximal portion being releasably secured together and the distal portion being disposable and the proximal portion being reusable.

Green et al. teach a distal portion being disposable and the proximal portion being reusable (col. 10, lines 47-51). It would have been obvious to one of ordinary skill in the art to provide a disposable distal portion and a reusable proximal portion, as taught by Green et al., to McPherson et al. since it was known in the art that disposable distal portions of medical devices is a solution to time-consuming sanitation of the distal ends prior to being introduced into the body.

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8. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) in view of **Pratt et al.** (U.S. Patent No. **5,607,436**).

Claims 9 and 14: Miller discloses the claimed device, except for a lever with a first end, a midsection, and a second end, a lead screw, and a nut driver.

Pratt et al. teach a lever **14** having a first end, a midsection, and a second end, the lever pivotally attached about a midpoint to the handle, the first end of the lever for gripping by hand, a lead screw **54** rotatably attached to interior of the handle, a nut driver, the second end of the lever pivotally attached to the nut driver, the nut driver for traveling along the lead screw, thereby turning the lead screw, and the lead screw attached to the rotator so that as the lever is depressed by hand the nut driver will travel along the lead screw towards the rotator thereby turning the rotator in the process (Figures 3-7). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first end, a midsection, and a second end, a lead screw, and a nut driver with all the above limitations, as taught by Pratt et al., to Miller since it was known in the art to use lever, screw, and driver mechanisms to advance fastening members from the interior of an applicator to the exterior.

Claim 11: Miller discloses the claimed device except for the lever having a midsection extension.

Pratt et al. teach a lever having a midsection extension **36** (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a midsection extension, as taught by Pratt et al., to Miller since it was



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known in the art that midsection extensions on levers are used in order to engage with the proximal, driver portion of the applicator.

Claims 12, 13, and 16: Miller discloses the claimed device, except for gear teeth formed within the interior of a handle, a spring loaded pawl pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism.

Pratt et al. teaches gear teeth **48** formed within the interior of a handle, a spring loaded pawl **40** pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism (Figure 3). It would have been obvious to one of ordinary skill in the art to provide the ratchet mechanism including the gear teeth and spring loaded pawl, as taught by Pratt et al., to Miller since it was known in the art to use ratchet mechanisms to restrict movement in one direction.

Claims 10 and 15: Miller discloses the claimed device, except for the lead screw being a high helix lead screw. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a high helix lead screw for the lead screw in Miller since it was known in the art that high helix angle thread screws are high efficiency using low rotational speeds.

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9. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller** (U.S. Patent No. **4,628,943**) and **Pratt et al.** (U.S. Patent No. **5,607,436**), as applied to Claim 14 above, and further in view of in view of **Knodel et al.** (U.S. Patent No. **5,487,500**).

Claims 17-18: Miller and Pratt et al. disclose the claimed device, including having a mid-section extension and a latch pawl cooperating with the teeth to prohibit the lever from backstroking until it has been completely depressed (see paragraph 7 above), except for a plurality of teeth being formed in the mid-section extension.

Knodel et al. teaches a mid-section extension with formed plurality of teeth (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of teeth, as taught by Knodel et al., to Miller and Pratt et al. since it was known in the art that teeth are used in ratchet and gear mechanisms which are used in applicators.

### ***Response to Arguments***

10. Applicant's arguments filed 06/09/2010 have been fully considered but they are not persuasive.

11. Applicant generally argues that Miller discloses a single fastener rather than a plurality of fasteners as necessitated by the claims. However, as maintained above, Miller discloses a fastener **36** ("bipolar pacing lead corkscrew") but lacks a plurality of fasteners, although the rotator is adapted to receive a plurality of fasteners for multiple actuations. It would have been

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obvious to one of ordinary skill in the art at the time of invention to provide a plurality of fasteners or a set of leads for delivery with Miller's applicator for further stimulation of tissue.

12. Applicant also generally argues that the rotator **54** in Miller is not axially stationary and does not eject the fastener **36**. However, the cited rotator is **60**, or "fixed, fluid tight plug **60**" which stays axially stationary (col. 6, lines 8-13), and the fastener **36** "is rotated through passageway **62** in a screw like manner and exits the passageway through an opening **64** in an insulative tip member **66** fixed about the plug **60**" (col. 6, lines 14-22), and therefore Miller reads on these limitations.

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734